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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,475	05/31/2001	Monika Lusky	017753-146	7808

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EXAMINER
MARVICH, MARIA

ART UNIT	PAPER NUMBER
1636	15

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/867,475	LUSKY ET AL.	
	Examin r	Art Unit	
	Maria B Marvich, PhD	1636	

-- The MAILING DATE of this communication app ars on th cov r sh et with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *31,34 and 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30,32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *09/463,486* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This office action is in response to an amendment filed 2/4/03. Claims 1-35 are pending in this application.

Election/Restrictions

Applicant's election with traverse of Group I in Paper No. 14 filed 2/4/03 is acknowledged. The traversal is on the grounds that a search and examination of the prior art for the groups would not be a serious burden on the examiner as such a search would overlap. Further, applicant argues that the groups share a special feature of being derived from or relating to the same chimeric adenoviral vector.

The argument is not found persuasive because of the divergent subject matter, the search would result in an undue burden. Please note that this application has been filed under the benefit under 35 U.S.C 120 and therefore, US restriction practice follows. While claiming the benefit of priority of a PCT application, defining the invention by its technical feature is not applicable. According to US restriction practice, inventions may be related and still be patentably distinct. See MPEP 802.01 and 806.05(h), "The term "distinct" means that two or more subjects as disclosed are related, for example, as combination and part (subcombination) thereof, process and apparatus for its practice, process and product made, etc., but are capable of separate manufacture, use, or sale as claimed, AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER (though they may each be unpatentable because of the prior art). It will be noted that in this definition the term related is used as an alternative for dependent in referring to subjects other than independent subjects." For reasons of record in the first office action, the

inventions of group I-III are distinct. In the present instance for example, it has been shown that the animal adenovirus of group II can be used in the method of group I but can also be used as a component in recombinant DNA technology to generate adenoviral gene transfer vectors.

The requirement is still deemed proper and is therefore made FINAL. Therefore, an examination of claims 1-30 and 32 follows. Claims 31 and 33-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 3, 6, 8, 20, 21 and 25-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23 and 25-29 of U.S. Patent No. 6,479,290. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are either anticipated by, or would have been obvious over the reference claims. Here, claim 23 of the US patent 6,479,290 recites a method for preparing a replication defective recombinant adenovirus (rAd) using two helper

virus of which one comprises a heterologous encapisdation sequence introduced into a first cell line, viral particles are recovered and introduced into a second cell line with the rAd. Claim 25 recites that the other helper is contained from a bovine adenovirus genome and claim 26 that it is also defective for E1. The first cell line, according to claim 27, is an MDBK or primary bovine cell line. Claims 23 and 25-29 of US patent 6,479,290 is the same as those in claims 1-3, 6, 8 and 20 of the instant application but the claims differ in that the method claims of the instant application recite that the rAd is a minimal adenoviral vector and the bovine adenoviral genome is BAV3. A minimal adenoviral vector is fully anticipated by claim 23 of US patent 6,479,290 in that it is a replication defective rAd. Using the specification as a dictionary, (column 4, line 25-26) the bovine adenoviral genome disclosed is BAV3. Therefore, it would have been obvious to modify the method claims of US patent 6,479,290 such that the bovine adenoviral genome is BAV3. One of ordinary skill in the art would have been motivated to make such a modification as it is disclosed to be the only bovine adenoviral genome contemplated by the invention.

Additionally, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the 6,479,290 patent, then two different assignees would hold a patent to the claimed invention of 6,479,290, and thus improperly there would be possible harassment by multiple assignees.

Claim Objections

Claim 22 and by dependency claim 23 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to the claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5, 11-13, 16, 19, 21, 26, 29 and 32 and by dependency 2-4. 6-10, 14, 15, 17, 18, 20, 22-25, 27, 28, 30 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague for reciting the genome of (i) and (ii) comprising. Do each of the first and second helper virus "genomes" or the combined "genome" of (i) and (ii) contain the recited characteristics?

Claims 1 and 21 are vague for reciting "deriving from" or "derives from". It is unclear how closely related the derived sequences are to the original adenovirus and it is also unclear what the functional and structural relationship between the original adenovirus and vectors "derived from" said adenovirus are. The metes and bounds of the claimed subject are unclear.

The term "different" in claim 1 is a relative term, which renders the claim indefinite. The term "different" is not defined by the claim, the specification does not provide a standard for

ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of the claim cannot be established.

Regarding claims 1 and 11, the phrase "optionally" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(b).

Claim 5 is unclear for reciting that first and/or second helper adenoviral vector is(are) wild-type adenovirus genomes(s). According to claim 1, the second adenovirus contains the encapsidation region from said first adenovirus genome. Therefore, the second adenovirus cannot be wild-type due to the recombinant nature of its encapsidation region.

~~Claim 13 recites the limitation "the E1 function" in claim 1. There is insufficient~~ antecedent basis for this limitation in the claim.

Regarding claims 12 and 19, the phrase "approximately" renders the claim indefinite. The term "approximately" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore, the metes and bounds of this claim cannot be established.

Regarding claim 16, the phrase "equivalent" renders the claim indefinite. The term "equivalent" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore, the metes and bounds of this claim cannot be established.

Claim 26 recites the limitation "the Ad5 E1 function" in 25. There is insufficient antecedent basis for this limitation in the claim.

Regarding claims 29 and 32 the phrase "substantially" renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of this claim cannot be established.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3291.

Maria B Marvich, PhD
Examiner
Art Unit 1636

April 21, 2003

JAMES KETTER
PRIMARY EXAMINER